U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

1. Program Code	2. Cross File / Related Files	3. File No.	4. G-DEP Identifier
	☐	[redacted]	[redacted]
5. By: Deborah A George, DI At: Orlando DO	☐	6. File Title PUBLIX SUPER MARKETS	
7. ☐ Closed ☐ Requested Action Completed ☐ Action Requested By:	☐	8. Date Prepared 07-21-2015	

9. Other Officers: GS Linda Stocum

10. Report Re: Scheduled Investigation, DEA #RP0331924-[redacted]

A. SYNOPSIS:

This investigation was initiated pursuant to the Fiscal Year 2015 Investigative Workplan, Orlando District Office, Diversion Control Group. PUBLIX SUPER MARKETS INC., 1950 Sand Lake Road, Bldg. 3, Orlando, Florida 32809 is registered with the DEA as a distributor in schedules 3, 3N, 4 and 5, DEA Registration Number RP0331924, expiration March 31, 2016.

The on-site portion of the Scheduled In-Depth Investigation was initiated on July 14, 2015 and concluded on July 15, 2015. Customer verifications were completed on July 21, 2015. Investigators conducted an accountability audit of seven controlled substances. The audit period extended from close of business July 3, 2014 to beginning of business July 14, 2015. The accountability audit disclosed no discrepancies.

This investigation is pending the Orlando District Office's receipt of additional information regarding the firm's system to detect and report suspicious orders, to include an outline of the firm's process and the specific person/department responsible for determining a suspicious order. The firm also agreed to provide requested due diligence files on DEA selected customers.

11. Distribution:	12. Signature (Agent)	13. Date
Division District Other [redacted]	Deborah A George, DI	07-23-2015
	14. Approved (Name and Title) /s/ Linda A Stocum, GS	15. Date 07-23-2015

DEA SENSITIVE
Drug Enforcement Administration

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B. ENCLOSURE PAGE:

1. NOI
2. Computation Chart
3. Alarm Contract
4. DEA 12-Listed Chemical Information

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C. BASIS FOR INVESTIGATION:

This investigation was initiated pursuant to the Fiscal Year 2015 Investigative Workplan for the Orlando District Office, Diversion Control Group. PUBLIX SUPER MARKETS INC. is registered with DEA Registration Number RP0331924 as a distributor in schedules 3, 3N, 4 and 5 at 1950 Sand Lake Road, Building 3, Orlando, Florida 32809, expiration date March 31, 2016.

D. SUBJECT FIRM'S BACKGROUND:

PUBLIX SUPER MARKETS INC, hereafter referred to as PUBLIX, is a wholesale distributor of food, health and beauty products, dry goods and controlled substances located at 1950 Sand Lake Road, Building 3, Orlando, Florida 32809. PUBLIX has occupied its current location for approximately 21 years. In 2005, the firm became registered with DEA as a distributor in schedules 3-5.

PUBLIX distribution center in Orlando distributes exclusively to 970 Publix retail pharmacies in six states; Florida, Alabama, Tennessee, Georgia, South and North Carolina. This is the firm's only distribution center that handles controlled substances in the United States. The distribution center does not distribute controlled substances to any non-company owned retail pharmacies.

PUBLIX was incorporated in the State of Florida in 1921 under document number 112252. The main branch headquarters office is located at 3300 Publix Corporate Parkway, Lakeland, Florida 33811.

The following individuals were provided as corporate officers:

- CEO William E. CRENSHAW, DOB: [redacted], SSN: [redacted]
- President Randall T. JONES, DOB: [redacted], SSN: [redacted]
- Officer/Treasurer David P. PHILLIPS, DOB: [redacted], SSN: [redacted]
- Senior Vice President John A. ATTAWAY Jr., DOB: [redacted], SSN: [redacted]
- Vice President of Pharmacy Fred J. OTTOLINO, DOB: [redacted] SSN: [redacted]
- Chairman of Board Carol Jenkins BARNETT, DOB: [redacted] SSN: [redacted]

A check in NADDIS revealed no derogatory information.

The following individuals were identified as principal management at the distribution center:

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- Superintendent Amado PLASCENCIA
- Department Manager Mark SHAIA
- Compliance & Regulatory Manager Laura SLONE
- Front Line Supervisor Christopher NIEBOER

A check in NADDIS revealed no derogatory information. Ms. SLONE is designated as the DEA contact person. Ms. SLONE is responsible for the firm's compliance with DEA record keeping and security requirements.

The distribution center operates with sixty eight full time employees and five part time employees. The Pharmacy Warehouse, which handles non-controlled and controlled substances, operates by utilizing 66 full time employees. The firm's business hours are Monday through Thursday 5:30am to 8:00pm and Friday and Sunday 5:30am to 4:00pm. Controlled substances account for approximately 8% of firm's business. Picking of controlled substances occurs continuously during work hours. For future reference, the firm representatives advised that the best time to conduct a closing inventory of controlled substance would be at 2pm, when an employee shift change occurs.

PUBLIX holds the following licenses:

State of Florida, Department of Health, Division of Medical Quality Assurance, License #221471, expiration September 30, 2015

State of Georgia, Wholesaler Pharmacy, Permit #PHWH002174, expiration June 30, 2017

State of Alabama, State Board of Pharmacy, Manufacturer/Wholesaler/Distributor Permit #193258, expiration date December 31, 2016

State of Alabama, State Board of Pharmacy, Precursor Chemical Supplier, Permit 700214, expiration date December 2016

State of Tennessee, Board of Pharmacy; Non-Resident Wholesaler/Distributor/Manufacturer, ID #0000002343, expiration date September 30, 2015

South Carolina Department of Labor, Licensing and Regulation, Board of Pharmacy, Non Resident Wholesale, Distributor, Manufacturers Permit #8528, expiration June 30, 2016

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South Carolina Department of Health and Environmental Control Bureau of Drug Control, Certificate of Registration in schedules 3-4, State Registration Number 40-008528, expiration date April 1, 2016

A check in DEA database indicated the following history:

[redacted]; Approval of Application, Distributor in schedules 3-5
[redacted]; Scheduled In-Depth, No violations
[redacted]; Scheduled In-Depth, No violations

In accordance with the reporting requirements of Memorandum dated October 27, 2009 from Deputy Assistant Administrator Joseph T. Rannazzisi, it should be noted that a review of DEA's database indicated that PUBLIX is not under a Memorandum of Agreement with DEA.

E. PERSON'S INTERVIEWED AND INDIVIDUAL RESPONSIBILITY:

On July 14, 2015 Diversion Investigator Deborah George and Group Supervisor Linda Stocum presented their credentials and issued a DEA Form 82, Notice of Inspection (NOI) to Laura SLONE (**Enclosure 1**). Investigator George informed Ms. SLONE to read and review the Notice, specifically, her firm's right pursuant to 1316.08(b). Ms. SLONE signed the NOI, hereby consenting to the inspection.

F. SCOPE OF INVESTIGATION:

The on-site portion of this investigation was initiated on July 14, 2015 and concluded on July 15, 2015. Verifications were completed on July 21, 2015. The controlled substance audit period extended from close of business July 3, 2014 to beginning of business July 14, 2015. The following controlled substances were selected to be audited based on current diversion trends/abuse and the firm's activities reported in ARCOS:

Schedule 3
Buprenorphine 8mg tablets 30 count bottle
Codeine with Acetaminophen 30/300mg tablets 1000 count bottle
Hydrocodone with Ibuprofen 7.5/200mg tablets 100 count bottle (until reclassified as schedule 2 in 10/2014)

Schedule 4
Diazepam 10mg 500 count bottle
Alprazolam 2mg 100 count bottle

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Schedule 5
Promethazine 10/6.25mg 473 ml bottle
Guaifenesin/Pseudoephedrine30mg/Codeine10mg 100mg 473ml bottle

Enclosure 2 is a copy of the computation chart.

G. RECORD KEEPING:

1. Initial Inventory:

An initial inventory date was chosen as close of business June 3, 2014. The inventory numbers were extracted from the firm's verified cycle count dated June 3, 2014. This cycle count documents the results of a physical count of the controlled substances taken at the close of business on June 3, 2014. Ms. SLONE verified that the initial inventory numbers were accurate. The firm's biennial inventory appeared to be in compliance with DEA requirements.

A review of the firm's records and inventories indicated that there were no hydrocodone products and tramadol products in inventory at the time of the rescheduling of these controlled substances.

Regarding the firm's internal auditing, ARCOS reportable items are reconciled monthly. The firm also conducts daily cycle counts based on product sales and receipts. All items with receipts or distributions from the previous day are counted and reconciled prior to shipping or processing for the day. Quarterly audits are also conducted by the audit department, which is located at the corporate office in Lakeland, Florida.

2. Closing Inventory:

Investigators George and Stocum with the assistance of Laura SLONE and Christopher NIEBOER conducted a closing inventory of nine controlled substances. Six of the nine controlled substances were selected to be audited. The additional non-audited controlled substances inventoried by Investigators were 96-100 count bottles of Phentermine 30mg tablets, item number 927982, NDC #10702-028-01 and 833-1000 count bottles of Tramadol 50mg tablets, item number 949608, NDC #6832-319-10. When sales for the day were taken into account, the physical count matched PUBLIX computer read-out of what was on hand at the beginning of business on July 14, 2015. Ms. SLONE and Mr. NIEBOER attested to the accuracy and completeness of the closing inventory. Closing Inventory numbers used for the audit are included on the Computation Chart which is Enclosure 2.

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3. Receipts:

The firm's primary receiving document is a purchase order which includes all the information required by DEA. The purchase order contains the name of the firm, order number, quantity, product description and the date received. The actual date an item is physically received is documented on this record. The invoice is attached to all other paperwork pertaining to the purchase of controlled substances, including the firm's purchase order, the vendor's shipping list, a freight bill prepared by PUBLIX and a freight log. The original purchase records for Schedules III–V controlled substances are maintained in a file stored in the controlled substances cage.

The firm also maintains computer-generated transaction reports in its computer database. The transaction reports show the product name; strength; size; invoice and purchase order; quantity; date the purchase order was closed; transaction date; and store identification. Investigators used these computer printouts to assist in the audit, comparing purchases to the original paperwork to verify receipt dates.

All deliveries of controlled substances are scheduled ahead of time. The appointment times are logged into the computer system and can be viewed up to one week in advance. Delivery drivers check in at the guard shack upon arrival, security signs the individual in then issues a temporary badge. The driver proceeds to the parking area and presents the ID to the security officer. The security officer verifies the purchase order and calls a receiving associate. There is an assigned receiving door where the carrier is sent once verification is completed. The receiving associate checks the purchase order and escorts the driver at all times. When the controlled substance is received, one of the individuals with access to the controlled substances cage is notified. PUBLIX has assigned a receiving center operator to log controlled substances purchase order information into the computer system. The computer system lists the controlled substances based on NDC number. All damaged items discovered are placed in the quarantine cage pending final disposition. All received goods that are not palletized are placed in a rolling cage and transported to the control substances cage area. All palletized items are escorted to the cage immediately after processing by the receiving associate. Once the order is verified, the invoice is stamped with the actual date received. All controlled substances are listed on a separate purchase order. The firm conducts a daily cycle count on all items which had a sale or delivery on that date to verify receipt and distribution information.

4. Production Records: NA

5. Distribution Records:

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The primary record for Schedule III-V distributions is the firm's computer generated invoice (pick slip) and the actual manifests, which are maintained by date and stored in the Information Services Department. All original hard copies go to the PUBLIX store the controlled substances are shipped to. The invoices are generated based upon computer orders transmitted to the Distribution Center from the individual pharmacies. According to Ms. SLONE, the firm verifies each customer's DEA registration prior to filling and processing an order. The firm's computer system will not generate an invoice if the DEA registration has expired. The DEA number and expiration date are printed on each shipping invoice.

All PUBLIX pharmacies use the firm's closed system, proprietary software to order controlled substances from the PUBLIX distribution center. The warehouse accepts or rejects the order from its stores. The firm generates pick slips via an interactive voice system used by warehouse personnel to fill orders. The distribution of each controlled substance is inventoried, cross checked and inspected prior to shipping. Each distribution is documented and tracked in the firm's computer system by item number. All controlled substances orders are pulled and checked by at least 3 individuals before being placed in totes and transferred to the shipping dock. The individuals are identified as a Selector, Order Checker and Dock Coordinator. All three individuals must verify the count before items are shipped.

Order pickers wear a wireless headset that is connected to a voice system. Once the picker receives the order, the computer generates a screen line for the same invoice. The picker logs on and begins picking. Once each item is picked it must be scanned by the picker and placed into a tote. If the item does not match the computer data, an error message is displayed and a voice message is relayed to the operator to choose the correct item. The scan code is based on the NDC number. The computer will not allow an invoice to be printed and closed until the error has been corrected. Orders are packed in a brown bag while in the cage but the box is not sealed until sent down the line to be boxed with non-controlled items. The shipping section closes all totes with a piece of PUBLIX security tape. Once the order is completed outside the cage an invoice is generated (computer invoice printed for the box). PUBLIX loads the totes containing controlled substances onto a short conveyor belt outside the controlled substances cage where the totes travel to the loading bays via the motorized conveyor belt system, stopping for verification in the distribution area. The conveyor belt is approximately 15 feet long and is within sight of operators. The single individual working in this area will not open any totes, but instead verify the label and order information on the outside of the tote against a printout. The totes are sent to the shipping department where they are sorted by route and funneled to the appropriate truck for delivery. Controlled substances totes do not sit on the loading bay. Every loading bay has cameras looking into the truck as it is loaded. The firm has a full time security staff monitoring the camera views. This information is digitally recorded and maintained for 60 days. When the semi-trailers are not being

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actively loaded and manned, the security door will be closed and locked. The firm utilizes a delivery truck service contracted through McKesson, Monday through Thursday. On Friday, the firm utilizes a third party carrier called Carrier Advertise Group. When goods are delivered, all loaded boxes will have the pharmacy designated on the box. A pharmacy associate must sign for the controlled substances. PUBLIX has made all carriers aware that all shipments should be delivered directly to the pharmacy. The driver obtains a signed freight log and delivery log from pharmacy personnel.

There were no theft or losses reported during the audit period. The firm is aware of the requirement to report any theft or loss of a controlled substance to DEA within 24 hours and to follow-up with a full report of the missing items via DEA's Theft or Loss system.

6. Records of Returned or Damaged Goods:

Damaged or expired goods that are received from the supplier will be returned to the supplier and a credit memo generated, or the products will be destroyed using an authorized destruction facility. The firm does not accept returns from their stores. All stores are internally equipped to handle the disposition of controlled substances in their possession. The return documents and credit memos are filed in the quarantine cage. The firm utilizes a quarantine cage to store substances that are in a holding status pending destruction or return.

7. ARCOS:

A review of the firm's ARCOS Participant File indicates that the firm electronically reports to ARCOS on a monthly basis with the last reporting date of June 30, 2015.

Prior to the inspection, the Orlando District Office obtained a certified ARCOS Report completed by the Pharmaceutical Investigation Section Targeting and Analysis pertaining to the firm's ARCOS reportable activity for the last two years. The ARCOS report verified that the firm had no strength, unit field errors, no dosage units or gram total miscalculations and no uncorrected error records. Pursuant to the Orlando District Office's request, ARCOS provided a list of the firm's top purchasers for the time period of June 10, 2013 to June 10, 2015 of three ARCOS reportable items: Codeine, Buprenorphine and Hydrocodone.

A review of the firm's ARCOS Transaction Purchase Summary indicates the firm's ARCOS reportable items as Butalbital, Codeine, Buprenorphine and Hydrocodone until it was reclassified as a schedule 2 controlled substance in October 2014. Codeine is currently the firm's largest ARCOS reportable item purchased. For the year of 2014, the firm purchased 3,264,960 dosage units of Codeine. As of May 2015, the firm has purchased

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2,618,400 dosage units, which indicates an increase from 272,080 dosage units to 523,680 dosage units purchased monthly. During the inspection, Ms. SLONE indicated that the firm's number of customers had increased by 38 from the previous year. A review of the ARCOS report documenting the firm's top purchasers of Codeine for the time period of June 10, 2013 to June 10, 2015 did not indicate any significant variances regarding the total dosage units purchased among the firm's customers.

During the inspection, Investigators requested a description of the firm's system to disclose suspicious controlled substance orders. In response, Ms. SLONE contacted and placed Chris Hewell, Pharm D, and Manager of Procurement on speaker phone. Mr. Hewell works at the firm's corporate office in Lakeland, Florida. Mr. Hewell agreed to provide Investigators with an overview of the firm's system. Mr. Hewell advised that he places all the orders for PUBLIX. Mr. Hewell advised that all controlled substances have a maximum shipment quantity for each customer. Mr. Hewell explained that the firm has software which generates orders and is programmed to establish a maximum order quantity based on a store's order history. If the customer exceeds the order, the over threshold amount is omitted from the order and an email is generated to alert the Pharmacy Supervisor. The firm has a threshold increase request process, which determines if an increase in threshold is necessary. If in the process, the order is deemed a suspicious order, it is reported to DEA. According to Mr. Hewell, the firm maintains a history of any/all the threshold adjustments for each customer. Mr. Hewell advised that the firm not only reviews the customer's purchase history but also has the ability to review the customer's dispensing activities.

Mr. Hewell agreed to provide Investigators with an outline of the process and the specific person/department responsible for determining and reporting a suspicious order. Additionally, Investigators requested due diligence files for ten of the firm's top customers for schedule 3-5 ARCOS reportable controlled substances. Mr. Hewell advised that he was aware of DEA requirements regarding the reporting of suspicious order and confirmed that PUBLIX has not reported any suspicious orders to the DEA.

During the discussion, Mr. Hewell was advised that DEA's database indicated that for the time period of January-July 2015, five PUBLIX retail pharmacies were among the top 100 purchasers of Oxycodone in the Orlando District Office's area of responsibility. Mr. Hewell indicated that he was surprised and requested further information. Investigators provided the following information: Publix #1201, 8075 SW Highway 200, Unit 111, Ocala, Florida 34481, BP8019362 (131,400 dosage units); Publix #0537, 3720 NW 13th Street, Suite 9, Gainesville, Florida 32609 BP4499427 (118,800 dosage units); Publix #0202, 3200 Lake Washington Road, Melbourne, Florida 32934, DEA #BP5797850 (99,000 dosage units); Publix #0419, 303 SE 17th Street, Ocala, Florida 34471, DEA #BP3072838 (96,200 dosage units); Publix #0527, 5801 SW 75th Street,

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Gainesville, Florida 32608, DEA #BP4477142 (90,700 dosage units). Investigators informed Mr. Hewell that DEA was advising the firm with the understanding that there may be a valid reason for quantities purchased.

8. Quotas: NA

H. DRUG AND EQUIPMENT SECURITY:

PUBLIX is located in an industrial park area on the South side of Orlando, FL. There are four main buildings on the site: grocery products, paper products, pharmacy warehouse and paper recycling, and the garage facility. The firm is surrounded by an 8 ft. galvanized chain link fence with wire on top, with access limited to a gate located beyond the guard station. Visitors are issued a pass after the appropriate member of the firm is contacted for approval. The firm is located in a low crime area. All employees and customers must enter through the front guard station and through the main entrance.

The Pharmacy Warehouse is building number 3 and is a freestanding single-story building. The building is constructed of block concrete reinforced with steel and measures approximately 29,000 square feet. The roof is constructed of 1½ inch metal standard decking, 4 ½ inch freezer insulation, and 1 inch rigid insulation decking, covered with tar and gravel. The main entrance to Building 3 faces east, and consists of a glass door set in a metal frame. There is one fire exit door constructed of metal and seven metal overhead doors located in the shipping and receiving areas. All doors are equipped with magnetic contact switches. The overhead doors are secured by sliding locks and padlocks, and additional alarm coverage utilizing a microwave sensor. The firm has exterior lighting located around the entire facility, and the parking lot has street lights as well. There is an alarm siren and strobe light on the exterior of the building. There is a small entry hatch on the roof of the pharmacy warehouse building with a magnetic contact switch and plastic seals on the door that are checked monthly. The hatch leads to the paper recycling area. Two cameras are mounted on the outside of the warehouse pharmacy on the front east side of the building.

Visitors are met at the main gate and escorted to the pharmacy warehouse (building three), where a second visitor's badge is issued and all personal items are stored in a designated locker. The main entrance to building three, opens to a self-contained lobby area. This area is equipped with a camera. All visitors are greeted by security personnel. An interior door is locked at all times and separates the lobby from the office area. Additionally, an internal door separates the office area from the warehouse. Employees must scan their photo ID badges to gain access throughout the firm. Employee movements throughout the warehouse are monitored by security personnel via a closed circuit camera system which is digitally recorded and reviewed. Security personnel conduct periodic walkthroughs of the facility.

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The firm's Schedule 3-5 controlled substances are stored in a cage located at the north end of the warehouse. The cage has three solid walls and one wall made of wire mesh. Two of the walls are constructed with 12 inch concrete block and one wall is constructed of 26 gauge steel skin and a 6 inch thick insulated wall panel. The front of the cage is constructed of 10 gauge steel mesh material, with approximately 2 X 1 inch openings. The horizontal steel bars are 57 inches apart and 2 ½ inches in diameter. The vertical steel square tube posts are 4 feet apart and 2 ½ inches in diameter. The vertical bars are bolted and brazed at all points to the concrete floor. The cage measures 36 feet deep, 30 feet high and 30 feet wide. The cage ceiling and cage door are constructed of the same black 10 gauge steel wire mesh. Entry to the cage requires a key and card access. When an employee is terminated all keys and access cards are collected and removed from the system.

The cage door has a magnetic contact switch. The cage extends to the building's perimeter walls on the north and west sides. The cage door, measuring 5' wide X 10' high, is constructed of #10 wire mesh and is located at the south end of the cage. The door is self-closing and self-locking and has a deadbolt lock. Alarm security in the cage is provided by a wide angle video camera located at the south end of the cage, as well as two 360 degree motion detectors located on the east side of the cage. There is a second sliding gate on the east side of the cage, measuring 2'8" X 8', which is protected by a contact switch. The cage is under a separate alarm zone. The cage also has one roll up door on the west wall used for palletized controlled substances. The roll up door is alarmed with a magnetic contact switch and key lock. There is a 360 degree motion detector located immediately outside the cage. Also outside the cage is a paper recycling area with a conveyor belt system and small door used for recycled card boxes. During hours of operation the conveyor door is open. The door leads to the recycling machine located in the recycling area and is 20ft off the ground. After business hours the door is sealed with a slide lock. The door is also alarmed with a magnetic contact switch and a motion detector mounted for complete door coverage. There are also three cameras mounted in the recycling area.

In addition to the schedules 3-5 controlled substances cage there is a quarantine cage. The quarantine cage is used for non-saleable and damaged items. The quarantine cage is constructed of #10 gauge wire mesh panels and located at the far south end of the warehouse. The cage is free standing and measures 14ft high, 24ft wide, and 25ft deep. The cage is bolted to the concrete floor and all bolts are brazed. The cage has a large sliding door next to a small man door. Both are constructed of 10 gauge steel mesh material. The sliding door is hinged and has sliders with a pad lock and contact switch. The main door is hinged with a self-closing and self-locking mechanism. The door also contains a magnetic contact switch and key lock. Access to the quarantine cage requires an access card and access code. The quarantine cage is a separate zone and the alarm keypad is mounted on the outside of the cage. There are two cameras that cover the entire quarantine

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cage area. Ms. SLONE and Mr. BAMBERGER are the only individuals with access to the quarantine cage. The cage has one motion detector located inside the cage providing complete coverage. The cage openings are 2 X 1 inches and the vertical posts are 2½ inches in diameter and mounted 57 inches apart.

The firm's security system consists of a BOSCH D7412G digital alarm communicator and TELGARD TG300 cellular system. The system is rated as a UL Grade A commercial burglary system. The system has a 24 hour battery backup installed and runs a self-test once every twenty four hours. The master control unit is located in the main entrance security area in the pharmacy warehouse. A copy of the rider to the firm's alarm system with TYCO Integrated Security is included as **Enclosure 3**. This documents the firm's alarm system to the pharmacy warehouse.

On July 14, 2015, Investigators conducted an alarm test and checked with the central station to confirm that the alarm signals were received accurately. The zone violations, including all cage motion detectors and door switches, were confirmed with the TYCO operator. In the event of an alarm, the Orange County Sheriff's Department will respond with response time estimated at 5 minutes or less.

PUBLIX employs security personnel to man the security office and guard station during business hours and the guard station 24 hours a day. All alarm signals are received at the security office and the monitoring station. Security personnel monitor all security cameras during business hours. Camera recordings are maintained for a minimum of sixty days.

The following individuals have access to the controlled substances cage and storage areas:

Laura SLONE-Compliance & Regulatory, DOB: [redacted], SSN: [redacted]
Mark SHAIA-Department Manager, DOB: [redacted] SSN: [redacted]
Amado PLASCENCIA-Superintendent, DOB: [redacted] SSN: [redacted]
Christopher NIEBOER-Front Line Supervisor, DOB: [redacted] SSN: [redacted]
Bradley Bennetts-Inventory Control Coordinator, DOB: [redacted] SSN: [redacted]
John Santiago-Inventory Control Coordinator, DOB: [redacted], SSN: [redacted]
Jason Tarrats-Inventory Control Coordinator, DOB: [redacted] SSN: [redacted]
Michael Bowman-Putaway/replenishment Forklift operator, DOB: [redacted] SSN: [redacted]
Janine Lockhart-Putaway/replenishment Forklift operator, DOB: [redacted], SSN: [redacted]
Lorenza Prater-Putaway/replenishment Forklift operator, DOB: [redacted], SSN: [redacted]
John Calcavecchia-Order Checker/Auditor, DOB: [redacted], SSN: [redacted]
Jason Birchmire-Order Checker/Auditor, DOB: [redacted], SSN: [redacted]

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Tisha Campos-Order Checker/Auditor, DOB [redacted], SSN: [redacted]
Thad Dixon, Order Checker/Auditor, DOB: [redacted] SSN: [redacted]
Sandra Miller, Stocker, DOB: [redacted], SSN: [redacted]
Zeljko Radmanovic, Selector, DOB: [redacted], SSN: [redacted]
Michael Bryski, Selector, DOB: [redacted], SSN: [redacted]
Carlos Morales, Selector, DOB: [redacted], SSN: [redacted]

A check in NADDIS revealed no derogatory information.

The corporate office conducts reference and background checks on all prospective employees. Additionally, new employees are subject to random drug screening. All prospective employees are interviewed at the pharmacy warehouse site and the human resources department at the corporate office receives a recommendation from the warehouse staff regarding the hiring of prospective pharmacy warehouse personnel.

I. INTELLIGENCE INFORMATION:

J. FOREIGN SUPPLIERS AND CUSTOMERS:

NA

K. DISCREPANCIES AND DISCUSSION WITH MANAGEMENT:

Based on the fact that the firm handles Listed Chemicals, Investigators provided Ms. SLONE with the following items: Notice-Ephedrine and Pseudoephedrine; Notice-Phenylpropanolamine; Notice: Special Surveillance; Notice-Iodine; Knowing Your Customer/Suspicious Orders Reporting; CFR 1310.02-Substances Covered and CFR 1310.04-Maintenance of Records. A DEA 12 **(Enclosure 4)** was issued to Ms. SLONE for the above items. Ms. SLONE was advised that DEA views receipt of these items and an acknowledgement that the firm will be aware/knowledgeable of the information contained within said documents.

L. VERIFICATIONS

On July 21, 2015, Investigator George verified the receipt of controlled substances the following invoiced controlled substances:

Publix Supermarket #0708; DEA Registration Number BP06721840; 1-Buprenorphine 8mg 30 count bottle on July 15, 2015; confirmed with Pharmacist Chris Rich

Publix Supermarket #0689; DEA Registration Number BP6586222; 1-Diazepam 10mg 500 count bottle on June 18, 2015; confirmed with Pharmacist Ashley Oliver

Publix Supermarket #0404; DEA Registration Number FP0319245; 1-Buprenorphine 8mg 30 count bottle on July 14, 2015; confirmed with Pharmacy Manager Linda Lloyd

M. SPECIAL ASSIGNMENTS

NA

This case is currently pending the Orlando District Office's review of requested information from the firm representatives, which includes a description of the firm's system to detect and report suspicious orders and due diligence files on ten selected customers.

INDEXING:

[redacted]

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

1. Program Code	2. Cross Related Files File	3. File No. [redacted]	4. G-DEP Identifier [redacted]
5. By: Deborah A George, DI At: Orlando DO	☐ ☐ ☐ ☐ ☐	6. File Title PUBLIX SUPER MARKETS	
7. ☒ Closed ☐ Requested Action Completed ☐ Action Requested By:		8. Date Prepared 07-24-2015	

9. Other Officers:

10. Report Re: Case Closing; DEA #RP0331924-[redacted]

SYNOPSIS:

Reference is made to a previous Report of Investigation dated July 21, 2015 under this file title and number. This ROI documents the Scheduled In-Depth Investigation of PUBLIX SUPER MARKETS INC., 1950 Sand Lake Road, Building 3, Orlando, Florida 32809, DEA Registration Number RP0331924. An accountability audit of selected controlled substances did not disclose any discrepancies. Of the records reviewed by Investigators, no record keeping violations were discovered. Additionally, no security violations were cited.

During this inspection, the firm agreed to provide additional information regarding the firm's system to disclose suspicious controlled substance orders, to include an outline of the firm's process and the specific person/department responsible for determining a suspicious controlled substance order. The firm also agreed to provide due diligence files on DEA selected customers. This ROI documents a description of the requested information received in it's entirely, on July 23, 2015.

In that no further action is anticipated, this case is considered closed.

DETAILS:

1. Reference is made to a previous Report of Investigation dated July 21, 2015 under this file title and number. This ROI documents the Scheduled In-Depth Investigation of PUBLIX SUPER MARKETS INC., 1950 Sand Lake Road, Building 3, Orlando, Florida 32809, DEA Registration Number RP0331924.

2. During the inspection, the firm agreed to provide the Orlando District Office with additional information regarding the firm's system to detect suspicious controlled substance orders, to include an outline of the firm's process and the specific person/department responsible for determining a suspicious controlled substance order. The firm also agreed to provide due diligence files on DEA selected customers.

11. Distribution:	12. Signature (Agent)	13. Date
Division District Other [redacted]	Deborah A George, DI	07-29-2015
	14. Approved (Name and Title) /s/ Linda A Stocum, GS	15. Date 07-30-2015

DEA SENSITIVE
Drug Enforcement Administration

REPORT OF INVESTIGATION *(Continuation)*	1. File No. [redacted]	2. G-DEP Identifier [redacted]
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3. Investigators utilized ARCOS Target and Analysis Unit's report documenting the firm's top purchasers of the firm's ARCOS reportable items for the time period of June 10, 2013 to June 10, 2015. Due diligence files were requested for the firm's top purchasers:

Codeine:

- Publix #0877, 212 Collier Parkway, Land O'Lakes, Florida 34639, DEA Registration Number BP8315649
- Publix #1212, 2202 Jim Redman Parkway, Plant City, Florida 33563, DEA Registration Number BP7347948
- Publix #1201, 8075 SW Highway 200, Unit 111, Ocala, Florida 34481, DEA Registration Number BP8019362

Buprenorphine:

- Publix #0537, 3720 NW 13th Street, Suite 9, Gainesville, Florida 32609, DEA Registration Number BP8019362
- Publix #0795, 1302 North Main Street, Gainesville, Florida 32601, DEA Registration Number BP7586994
- Publix #0527, 5801 SW 75th Street, Gainesville, Florida 32608, DEA Registration Number BP4477142

Hydrocodone (until rescheduled as schedule 2 in October 2014):

- Publix #1037, 7749 Normandy Boulevard, Jacksonville, Florida 32221, DEA Registration Number BP9535519
- Publix (no store number), 650 West 23rd Street, Panama City, Florida 32405, DEA Registration Number BP3916458
- Publix #1444, 299 East International Speedway Boulevard, Deland, Florida 32724, DEA Registration Number BP3614042
- Publix #0801, 2250 South Ferdon Boulevard, Crestview, Florida 32536, DEA Registration Number BP7563578

3. In response to the request, Mr. Chris Hewell, PharmD, Manager of Procurement, Publix Supermarkets electronically sent the Orlando District Office a spreadsheet indicating dosage unit thresholds for each controlled substance on the above referenced pharmacies. The spreadsheet lists the following information: store number, controlled substance, date, ordered quantity, shipped quantity and threshold quantity.

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4. The firm also provided a history of the pharmacies' request for a threshold increase made via a thread of emails. The emails were initiated by a "Pharmacy Controlled Substance Threshold Change Request Form," which consists of the following information: Date, Store number, Name of Requesting Pharmacist, store address, Pharmacy DEA Number, McKesson Account #, Description of Product, Desired Threshold Increase and Reason for Change Request. **Attachment A** consists of two examples of the above.

5. Regarding additional information on the firm's system, Mr. Hewell provided a thirty page document entitled "Controlled Substance Anti-Diversion Processes." This document was identified by Mr. Hewell, as an overview of the firm's controlled substance auditing process and the responsible parties. The document consists of procedures used to prevent the diversion of controlled substances performed by multiple departments, including Loss Prevention, Pharmacy Operations, Pharmacy Procurement Department and Warehousing and Distribution. In the document, it states that Corporate Loss Prevention Support creates a Weekly Pharmacy Adjustment Exception Report, which analyzes exception results for concerns, patterns or unexplained activity occurring at a retail pharmacy. Additionally, each month, the Procurement Department, reviews each pharmacy dispensing history for highly abused/diverted controlled substances. This information is reported to be used by the Operations Department to identify and evaluate trends in dispensing (percentage of cash prescriptions and percentage of controlled substances), compare pharmacy controlled substance dispensing from similar volume pharmacies and to recommend threshold adjustments. The document indicates that a review of the count and percentage of all controlled substance prescriptions dispensed; a count and percentage of individual controlled substance prescriptions; and a count and percentage of controlled substance prescription filled cash or discount card is conducted. This document also identifies the process for identifying the monthly thresholds as an analysis of historical purchasing patterns, actual pharmacy usage, and usage compared to average Publix pharmacy. If a monthly threshold is met by a customer, no additional orders will be shipped for the remainder of the month. An email notification is sent to the pharmacy and Pharmacy Supervisor, when the pharmacy is approaching their threshold and when it exceeded threshold. If a pharmacy has exceeded, the pharmacy supervisor should visit the pharmacy to determine the need for the threshold increase and if any suspicious dispensing activities are taking place. If suspicious activity is confirmed, the pharmacy supervisor must notify their Pharmacy Operations Manager and Manager of Procurement immediately. The Manager of Procurement must notify the Orlando DEA Office immediately and de-authorize any implicated controlled substances from being shipped. **Attachment B** is a copy of the document. Mr. Hewell also provided a flow chart of the system which identifies each Department's responsibility. **Attachment C** is the chart.

6. During the discussion with Management, Group Supervisor Stocum and Investigator George advised Compliance & Regulatory Manager Laura Slone, Department Manager Mark Shaia and Front Line Supervisor

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Christopher Nieboer that DEAdoes not approve or disapprove of a registrant's system of disclosing suspicious orders. The firm representatives were reminded that the firm's system is required to be efficient in reporting suspicious orders to DEA. It should be noted that Mr. Hewell was also advised of the above during a conference call with GS Stocum and Investigator George on July 14, 2015.

7. In that no further action is anticipated, this case is considered closed.

INDEXING:

[redacted]

ATTACHMENTS:

A. Examples of threshold request
B. Controlled Substance Anti-Diversion Processes
C. Flow Chart